

### AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-43. (Canceled)

44. (Currently amended) A method of treating cancer comprising administering to a patient in need thereof:

(a) an admixture comprising a cancer or tumor antigen expressed by cells of the cancer to be treated and a microfluidized antigen formulation comprising:

- (i) a stabilizing detergent,
- (ii) a micelle-forming agent, and
- (iii) a biodegradable and biocompatible oil,

said antigen formulation being formulated as a stable oil-in-water emulsion;

wherein said admixture is administered to said patient in an amount sufficient to induce a cytotoxic T-lymphocyte response in said patient which is specific for the cancer or tumor antigen contained in said admixture, and

(b) a therapeutically effective amount of at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of transforming growth factor  $\beta$  (TGF $\beta$ ) specifically, which agent is selected from the group consisting of an anti-TGF $\beta$  antibody, a TGF $\beta$ R-fusion protein, a TGF $\beta$  analog, a TGF $\beta$  binding protein, and a TGF $\beta$ R blocking antibody;

wherein the antigen-containing admixture and the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF $\beta$  are administered sequentially or concurrently, and in any order.

45. (Previously presented) The method of claim 44, wherein the antigen-containing admixture and the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF $\beta$  are administered sequentially.

46. (Previously presented) The method of claim 44, wherein the antigen-containing admixture is administered intradermally, intramuscularly or subcutaneously and

the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF $\beta$  is administered intravenously.

47. (Canceled)

48. (Currently amended) The method of claim 47 ~~44~~, wherein the at least one agent which is capable of neutralizing, blocking, antagonizing, or down regulating the activity or preventing activation of TGF $\beta$  is a thrombospondin peptide or a TGF $\beta$ R Fc-fusion protein.

49. (Previously presented) The method of claim 44, wherein the admixture comprises a cancer or tumor antigen selected from the group consisting of gp100, MART-1/Melan A, gp75, tyrosinase, melanoma proteoglycan, MAGE, BAGE, GAGE, RAGE, N-acetylglucosaminyltransferase-V, mutated B-catenin, mutated MUM-1, mutated cyclin dependent kinases-4, p21 ras, BCR-abl, p53, p185 HER2/neu, mutated epidermal growth factor receptor, carcinoembryonic antigens, carcinoma associated mutated mucins, Epstein Barr nuclear antigen (EBNA) gene products, papillomavirus E7 protein, papillomavirus E6 protein, prostate specific antigens, prostate specific membrane antigen, and prostate carcinoma tumor antigen-1 (PCTA-1).

50. (Previously presented) The method of claim 44, wherein the cancer is selected from the group consisting of breast cancer, brain cancer, cervical cancer, leukemia, lymphoma, prostate cancer, skin cancer, colon cancer, lung cancer, ovarian cancer, pancreatic cancer, liver cancer, bladder cancer, kidney cancer, myeloma, colorectal cancer, nasopharyngeal carcinoma, or endometrial cancer.

51. (Previously presented) The method of claim 44, wherein the detergent is provided in an amount ranging from approximately 0.05 to 0.5%.

52. (Currently amended) The method of claim ~~52~~ 51, wherein the amount of detergent is about 0.2%.

53. (Currently amended) The method of claim 44, wherein the detergent is selected from the group consisting of ~~TWEEN 80~~ sorbitan-mono-9-octadecenoate-poly(oxy)-

~~1,2-ethanediyl, TWEEN-20 polyoxyethylenesorbitan monolaurate, TWEEN-40 polyoxyethylenesorbitan monopalmitate, TWEEN-60 polyoxyethylenesorbitan monostearate, Zwittergent-3-12 N-dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, TEEPOL-HB7 alkyl (C<sub>9</sub>-C<sub>13</sub>) sodium sulfates, and SPAN-85 sorbitan trioleate.~~

54. (Previously presented) The method of claim 44, wherein the micelle-forming agent has a hydrophile-lipophile balance of between 0 and 2.

55. (Previously presented) The method of claim 44, wherein the amount of the micelle-forming agent ranges from 0.5 to 10%.

56. (Previously presented) The method of claim 55, wherein the amount of the micelle-forming agent ranges from 1.25 to 5%.

57. (Canceled)

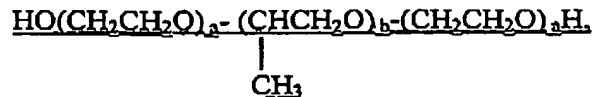
58. (Previously presented) The method of claim 44, wherein the amount of oil ranges from 1 to 10%.

59. (Previously presented) The method of claim 58, wherein the amount of oil ranges from 2.5 to 5%.

60. (Previously presented) The method of claim 44, wherein the oil exhibits a melting temperature of less than 65°C.

61. (Previously presented) The method of claim 44, wherein the oil is selected from the group consisting of squalane, eicosane, tetratetracontane, pristane, and vegetable oils.

62. (Currently amended) The method of claim 44, wherein the antigen-containing admixture comprises ~~TWEEN-80 sorbitan-mono-9-octadecenoate-poly(oxy)-1,2-ethanediyl, poloxamer-401~~ a block copolymer having the structure:



wherein a and b are such that the average molecular weight of the polyoxypropylene blocks in the molecule is 4000 and approximately 10% of the molecular weight of the copolymer is composed of the polyoxyethylene blocks, and squalane.

63. (Currently amended) The method of claim 44, wherein the antigen-containing admixture contains no more than 20 micrograms of an immunostimulating peptide muramyl dipeptide.

64. (Currently amended) The method of claim 44, wherein the antigen-containing admixture lacks an immunostimulating peptide muramyl dipeptide.